REMARKS

A. Status of the Claims

Claims 1-27 were filed with the case and are presented herein for reconsideration.

B. Objection to the Claims

The claims are objected to for including a blank where the ATCC accession number should be. In response, Applicants note that the accession number will be inserted upon the allowance of the case. Removal of the objection is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects the claims as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Action rejects the claims based on the lack of recitation of a deposit of seed for the claimed variety. In response, it is noted that a deposit of 2,500 seeds of claimed soybean variety will be made with the ATCC in accordance with all of the rules, including accessibility of seed to the public without condition, and the claims will be amended to recite the corresponding ATCC accession number. In view of the foregoing, removal of the rejection is respectfully requested.

D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 9-27 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey to one of skill in the art that Applicant was in possession of the claimed subject matter at the time the specification was filed. In particular it is asserted that claims to F1 hybrids, plants of variety soybean variety 0137335 comprising a single locus conversion, and methods of plant

breeding comprising use of variety 0137335 as starting material lack written description based on an asserted failure to describe all of the second parent plants that could possible be employed in any steps and all of the structural characteristics of any plant that could be employed at any step of any method.

In response, it is noted that all of the issues raised by the written description rejections have been decided in the favor of Applicants by the Board of Patent Appeals in six cases directed to corn varieties and containing claims of substantially similar scope: Appeal Nos: 2004-1503 (Ser No. 09/606,808), 2004-1506 (Ser. No. 09/788,334), 2004-1968 (Ser. No. 10/000,311), 2004-2317 (Ser. No. 09/771,938), 2004-2343 (Ser. No. 09/772,520); and 2005-0396 (Ser. No. 10/077,589) (collectively "the corn variety appeals"). Although directed to corn plants instead of soybean plants, the claims at issue in these cases were substantially identical in scope to those of the current case. In particular, essentially identical written description rejections were raised in the prior cases relative to the current case on the same material facts. While the Board decisions have yet to be published and designated binding precedent, these cases presented the same factual and legal questions at issue here and thus are dispositive on the issues raised and may not be disregarded.

1. Hybrid Plants and Seeds Have Been Fully Described

a. The issue has been decided in Applicants favor by the Board

In the corn variety appeals, essentially identical rejections were raised based on an alleged lack of written description for F1 hybrid plants. Specifically, it was alleged that the F1 hybrid plants only have as half of their genome the genome of the parent plant of interest and the remaining portion was not described, and thus written description is lacking, despite the fact that no particular second hybrid plant is required by the method. *See* Appeal No. 2004-1968, p. 17, 1st ¶.

The Board rejected this reasoning, noting that, as here, the claims require no particular second parent of the F1 hybrid and the Action had already acknowledged written description for the variety of interest. The Board thus held that "there can be no doubt that the specification provides and adequate written description of this corn variety." *Id.* at p. 18, 1st ¶. As explained by the Board, the purpose of the written description requirement is to "ensure that the right of the scope to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Id.* at 2nd¶. Here, as in the corn variety appeals, the claimed F1 hybrid plants must have the admittedly described variety of interest as one parent, and thus the claims do not overreach the scope of the inventor's contribution and are fully described.

While the Board noted as an aside that the specification at issue described an exemplary hybrid, this does not change the analysis because the decisions did not turn on the issue. The dispositive issue was the Board's rejection of the notion that Applicants must define every possible second hybrid parent plant and the morphological characteristics of the progeny thereof. In particular, the Board stated that it "disagree[d] with the examiner's conclusion (id.) that '[t]he fact that any hybrid plant will inherit half of its alleles from [the variety of interest] then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants." *Id.* at p. 17, 2nd ¶. As this is the crux of the current rejection, removal of the rejection is respectfully requested on the same basis.

b. The claimed hybrid plants each share the genetic complement of soybean variety 0137335

The Action rejects claims directed to hybrid seeds and plants or parts grown therefrom produced with soybean plant 0137335 as one parent. Applicants have fully described this subject matter in compliance with the written description requirement of 35 U.S.C. §112, first

paragraph. As indicated in the specification, soybean plant 0137335 is an inbred plant. All of the claimed hybrid plants having 0137335 as a parent will therefore contain a haploid copy of the same genome as soybean plant 0137335. That is, because 0137335 is an inbred soybean plant, hybrid soybean plants derived therefrom will have as half of their genetic material a uniform genetic contribution representing the haploid genome of soybean plant 0137335, save the possibility of the rare spontaneous mutation or undetected segregating locus.

As to the other genetic complement, this can be from ***any*** second soybean plant. That is, a hybrid soybean plant will be produced any time soybean plant 0137335 is crossed to a different plant. Since any second plant may be used, Applicants cannot be said to lack possession of this element. It is a gross understatement to say that soybean plants in general were known in the art. Soybean varieties have been known in the art for as long as soybeans have been cultivated. Applicants therefore do not lack written description for this element.

The genetic complement of soybean plant 0137335 present in the claimed hybrid plants represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from all other plants in full compliance with the written description requirement. The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having 0137335 as one parent

share the structural feature of having the genetic complement of 0137335. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

c. The entire genetic complement of soybean variety 0137335 is described by way of the proffered deposit of seed

The Action alleges that Applicants have not disclosed the genetic complement shared by each of the claimed hybrid plants and seeds. It is thus alleged that the genetic contribution of soybean variety 0137335 could not be distinguished and is not described. This is incorrect, however, as Applicants describe the entire genetic sequence of soybean variety 0137335 by way of the proffered deposit of seed of the variety. Applicants have stated on the record that a deposit of seeds of soybean variety 0137335 will be made with the ATCC and that a Declaration would be submitted certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809. This statement satisfies the deposit requirement for purposes of examination.

The Federal Circuit has held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Specifically, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that "as those bacteria were deposited, their ***bacterial genome is accessible*** and, under our holding today, they are ***adequately described in the specification by their accession numbers***." (emphasis added) *Id.* In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome

of one strain of *N. gonorrhoeae*. *Id.* In the instant case, even more effort would be required, as soybeans are a higher life form with a more complex genome than the bacteria deposited in *Enzo*.

The fact that the deposit here will be made after the filing date of the application has no bearing on written description, as the Federal Circuit has noted that insertion of an accession number for a deposit after the filing date adds no new matter to a case provided the deposited subject matter is clearly identified in the application. See *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985) ("....an accession number and deposit date add nothing to the written description of the invention"). Applicants have fully described the shared structure of the claimed hybrid plants at the nucleic acid level and thus have fully complied with 35 U.S.C. §112, first paragraph.

d. The allegedly non-described portion of the hybrid plant genome is non-critical and well known in the art and thus fully described in compliance with 35 U.S.C. §112, first paragraph

The Action asserts a lack of written description based on a failure to specify the second parent. However, no particular second plant is required by the claims and soybean plants in general were well known to those of skill in the art. ***Any*** different soybean plant may be crossed with soybean variety 0137335 to produce the claimed hybrid soybean seed and plant. Which second plant is crossed with soybean variety 0137335 is irrelevant to the production of a hybrid soybean plant, because a hybrid is produced whenever soybean variety 0137335 is crossed to a different variety. What is therefore relevant is whether soybean plants in general were known.

It is an understatement to say that soybean plants in general are known to those of skill in the art. This is evidenced by a review of the USPTO website patent database, a brief search of which reveals utility patents issued on more than 250 different soybean varieties prior to the filing date of the instant application, each of which have been deposited with the ATCC in

compliance with 35 U.S.C. §112, first paragraph. Any of these varieties, or the many hundreds or thousands of other soybean plants that have been known since the dawn of agriculture could be used to produce an F1 hybrid plant having soybean variety 0137335 as one parent, and each of these would share the genetic complement of 0137335 as well as that of the second, known plant.

Written description must be reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, all of the structural characteristics of the claimed hybrid plants and seeds have been fully described in compliance with the written description requirement.

e. The expression of the genetic complement of soybean variety 0137335 is irrelevant

It has been asserted that claimed hybrid plants have not been described because information is not provided regarding the morphological and physiological traits of the hybrid plants and that how the genes that are inherited would be expressed or would interact has not been shown. However, this is irrelevant because Applicants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level by way of the proffered seed deposit. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing provides an even better description by going to the source of traits, yielding concrete values.

The law further makes no distinctions regarding the ***manner*** in which applicants choose to describe their invention. Rather, an applicant must merely describe the claimed subject matter by "***whatever characteristics*** sufficiently distinguish it." (emphasis added) *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). The genome of a plant fully distinguishes it just as DNA testing does for humans. Here, Applicants have described the entire genetic complement of parent plant 0137335 that will be comprised in the claimed hybrid plants by way of the proffered biological deposit. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002). This can be identified using any of the well known techniques described by Applicants. The claimed subject matter has therefore been fully described and removal of the rejection is respectfully requested.

2. Methods of Plant Breeding Comprising Use of Soybean Variety 0137335 Are Fully Described

a. The issue has been decided in Applicants favor by the Board

Essentially identical written description rejections were raised by the examiner in Appeal No. 2004-1968 of claims drawn to a method of breeding corn plants comprising use of the variety of interest as starting material. As here, it was argued that written description is lacking because the intermediate plants at each step of the method allegedly must be described to satisfy written description and that such plants had not been defined, regardless of the fact that in both cases the only starting material required by the claims was the variety of interest, which was admittedly fully defined. *See* p. 12-15. As explained by the Board in Appeal No. 2004-1968, the position of the examiner was that "not only does appellant have to provide a written description of the starting [variety of interest], but appellant must also look into the future to determine every other potential corn plant that someone may wish to cross with the [variety of interest], and provide written descriptive support for not only every other corn plant that could be crossed with

this line, but also the resulting progeny of each cross." *Id.* at p.13, 1st full ¶. In the context of plant breeding to introduce transgenes, it was also alleged that written description was lacking because every possible transgene or single locus conversion that could be introduced into the plant had not been defined and thus every possible phenotype that such a plant could comprise was not defined. *See Id.* at p.14-15.

The Board rejected this reasoning, noting that, given the acknowledgement of written description for the variety of interest, Applicants were also in possession of a method of using that plant for crossing with any other plant to produce an inbred plant as set forth in the claims. The Board thus concluded that appellant established with reasonable clarity that they were in possession of the invention. *Id.* at p.14, 1st full ¶. In the context of methods of introducing transgenes, the Board noted that no evidence was provided to support the rejections or inadequacy of written description for the claims. *Id.* at p.15, 1st full ¶. The Board thus reversed the written description rejections. *Id.* at p.18, 3rd ¶.

The same issues have been presented here on claims of an essentially identical scope. As the Board has already decided this issue in Applicants favor, removal of the rejection is respectfully requested.

b. The rejection has not been supported

Applicants understand that it is the position in the Action that written description is lacking for the method claims because written description must be provided for each intermediate product in a method claim in the same manner as if the particular product was claimed as a composition of matter. That is, Applicants understand that the position taken is that it is not sufficient to describe all of the starting materials for a process and all of the steps carried out on the starting materials, but rather that the structural characteristics of any product made at any intermediate or penultimate step must be described as if claimed as a composition of matter.

Applicants submit that this is incorrect and, more significantly, note that this rejection has not been adequately set forth on the record. No basis in law or fact has been given for maintaining the rejection.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections have not been so supported and therefore the standards of the APA have not been met. Removal of the rejection is thus respectfully requested.

c. Product claims and process claims are not analyzed in the same manner for purposes of the written description requirement

It is black-letter law that the written description requirement is applied only with respect to what is claimed. For example, in *Vas-Cath, Inc. v. Mahurkar*, the Federal Circuit noted that there is no legally recognizable or protected essential element of the invention in a combination patent. 935 F.2d 1555, 1565 (Fed. Cir. 1991). Rather, it was held that the applicant must show with reasonable clarity that he or she was in possession of the invention, and that the invention for purposes of the written description requirement is ***what is claimed***. *Id.* at 1564. In the instant case, methods of plant breeding comprising use of soybean variety 0137335 are claimed but the Action nonetheless appears to take the position that the 0137335 derived soybean plant itself is being claimed and therefore must be described as if the subject of a process or product by process claim. This directly contradicts the prohibition against applying written description with

respect to unclaimed subject matter. It is respectfully submitted that the approach confuses product by process claims, which claim a product and thus may be analyzed in this manner, with a process claim in which it is only the recited steps and necessary staring materials that must be described.

The products of intermediate and penultimate steps of the claimed methods are inherently produced by following the recited steps using starting materials that are fully described, namely variety 0137335 and ***any*** different second soybean plant. All that is required to complete the claimed methods is to carry out the breeding steps recited. The only starting materials for the claims are: (1) soybean variety 0137335, (2) any second soybean plant, or (3) a soybean plant that is produced by the preceding method step. Therefore, all materials required by the method have been fully described.

It must further be noted that soybean breeding is well known to those of skill in the art. Without it, there would not be commercial soybean varieties. This is evidenced by the more than 250 issued patents to inbred soybean varieties discussed above. The specification also describes such techniques for breeding soybean varieties in great detail. Written description must be viewed against this backdrop. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993).

3. Single Locus Conversion are Fully Described and Plants Comprising Transgenes are Fully described

a. The issue has been decided in Applicants favor by the Board

In the corn variety appeals substantively the same scope of subject matter claimed here was rejected for lack of written description on the same grounds as here. For example, claim 26 in Appeal No. 2004-1968 was directed to "The corn plant, or parts thereof, of claim 2, wherein

the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements." Claim 27 was directed to "A method for producing a corn plant that contains in its genetic material one or more transgenes, comprising crossing the corn plant of claim 26 with either a second plant of another corn line, or a non-transformed corn plant of the line LH321, wherein progeny are produced, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element." Similarly, claim 28 was directed to "Corn plants, or parts thereof, produced by the method of claim 27."

The Board specifically reversed written description rejections made of these claims on the same grounds presented here. The same operative set of facts and legal questions are presented here. Removal of the rejection is thus respectfully requested.

b. The claims are described

The Action rejects claims directed to the claimed plants comprising single locus conversions or transgenes on the basis that the specification does not adequately describe transgenes for use in the claimed methods. However, Applicants note that transgenes were well known to those of skill in the art and the specification discloses well more than a representative collection of transgenes sufficient to describe this subject matter. To demonstrate this, a list of transgenes and accompanying references to published citations known prior to the filing date of the application is shown below:

marker genes such as neomycin phosphotransferase II (nptll) under the control of plant regulatory signals that confers resistance to kanamycin (Fraley et al., Proc. Natl. Acad. Sci. U.S.A., 80:4803, 1983); a hygromycin phosphotransferase gene which confers resistance to the antibiotic hygromycin (Vanden Elzen et al., Plant Mol. Biol., 5299, 1985); marker genes of bacterial origin that confer resistance to antibiotics including gentamycin acetyl transferase, streptomycin phosphotransferase, aminoglycoside-3'-adenyl transferase, the bleomycin

resistance determinant (Hayford et al., Plant Physiol. 86:1216, 1988; Jones et al., Mol. Gen. Genet., 210:86, 1987; Svab et al., Plant Mol. Biol. 14:197, 1990; Hille et al., Plant Mol. Biol. 7:171, 1 986); selectable marker genes conferring resistance to herbicides such as glyphosate, glufosinate or broxynil. (Comai et al., Nature 317:741-744, 1985; Gordon-Kamm et al., Plant Cell 2:603-618, 1990; Stalker et al., Science 242:419423, 1988); mouse dihydrofolate reductase, plant 5-enolpyruvylshikimate-3-phosphate synthase and plant acetolactate synthase (Eichholtz et al., Somatic Cell Mol. Genet. 13:67, 1987; Shah et al., Science 233:478, 1986; Charest et al., Plant Cell Rep. 8:643, 1990); genes for screening presumptively transformed cells such as P-glucuronidase (GUS), P-galactosidase, luciferase and chloramphenicol and acetyltransferase (Jefferson, R.A., Plant Mol. Biol. Rep. 5387,1987; Teeri et al., EMBO J. 8:343, 1989; Koncz et al., Proc. Natl. Acad. Sci U.S.A. 84:131, 1987; DeBlock et al., EMBO J. 3:1681, 1984); a gene encoding Green Fluorescent Protein (GFP) (Chalfie et al., Science 263:802, 1994); a gene from maize which responds to benzenesulfonamide herbicide safeners (Hershey et al., Mol. Gen Genetics 227:229-237, 1991; Gatz et al., Mol. Gen. Genetics 243:32-38, 1994); constitutive promoters including , but not limited to, the promoters from plant viruses such as the 35S promoter from CaMV (Odell et al., Nature 313:810-812, 1985) and the promoters from such genes as rice actin (McElroy et al., Plant Cell 2:163-171, 1990), ubiquitin (Christensen et al., Plant Mol. Biol. 12:619-632, 1989, Christensen et al., Plant Mol. Biol. 18:675-689, 1992) pEMU (Last et al., Theor. Appl. Genet. 81581-588, 1991), MAS (Velten et al., EMBO J. 3:2723-2730, 1984), maize H3 histone (Lepetit et al., Mol. Gen. Genetics 231:276-285, 1992; Atanassova et al., Plant Journal (3): 291-300, 1992), and ALS genes (PCT application W096/30530); tissue-specific or tissue-preferred promoters including, but not limited to, a root-preferred promoter - such as that from the phaseolin gene (Murai et al., Science 23:476482. 1983; Sengupta-Gopalan et al., Proc. Natl. Acad. Sci. U.S.A. 82:3320-3324, 1985), a leaf- specific and light-induced promoter such as that from cab or rubisco (Simpson et al., EMBO J. 4(11):2723-2729, 1985; Timko et al., Nature 318579-582, 1985), an anther-specific promoter such as that from LAT52 (Twell et al., Mol. Gen. Genetics 21 7:240-245, 1989), a pollen-specific promoter such as that from Zm13 (Guerrero et al., Mol. Gen. Genetics 244:161-168, 1993) or a microspore-preferred promoter such as that from apg (Twell et al., Sex. Plant Reprod. 612 1 7-224, 1993); a signal sequence that directs a polypeptide to either an intracellular organelle or subcellular compartment or for secretion to the apoplast (Becker et al., Plant Mol. Biol. 20:49,1992; Close, P.S., Master's Thesis, Iowa State University, 1993; Knox, C., et al., "Structure and Organization of Two Divergent Alpha-Amylase Genes from Barley", Plant Mol. Biol. 9:3-17, 1987; Lemer et al., Plant Physiol. 91:124-129, 1989; Fontes et al., Plant Cell 3:483-496, 1991; Matsuoka et al., Proc. Natl. Acad. Sci. 88:834, 1991; Gould et al., J. Cell. Biol. 108:1657, 1989; Creissen et al., Plant J. 2:129, 1991, Kalderon, et al.); a short amino acid sequence able to specify nuclear location, (Cell 39:499-509, 1984; Steifel, et al.); a maize cell wall hydroxyproline-rich glycoprotein gene in early leaf and root vascular differentiation (Plant Cell 2:785-793, 1990); plant disease resistance genes such as those activated by specific interaction between the product of a disease resistance gene (R) in the plant and the product of a corresponding avirulence (Avr) gene in the pathogen (Jones et al., Science 266:7891, 1994), the tomato Cf-9 gene for resistance to Cladospotium (Martin et al., Science 262: 1432, 1993), a tomato Pto gene for resistance to Pseudomonas syringae pv. (Lblindrinos et al., Cell 78: 1 089, 1994), Arabidopsis RSP2 gene for resistance to Pseudomonas syringae; a gene conferring resistance to a pest, such as soybean cyst nematode (PCT Application W096/30517; PCT Application W093/19181), a *Bacillus thuringiensis* endotoxin (Geiser et al., Gene 48:109, 1986), a lectin (Van Damme et al., Plant

Molec. Biol. 24:25, 1994, a vitamin-binding protein such as avidin (PCT application US93/06487); an enzyme inhibitor, for example, a protease or proteinase inhibitor or an amylase inhibitor (Abe et al., J. Biol. Chem. 262:16793, 1987), a nucleotide sequence of rice cysteine proteinase inhibitor (Huub et al., Plant Molec. Biol. 21:985, 1993), a nucleotide sequence of encoding tobacco proteinase inhibitor I (Sumitani et al., Biosci. Biotech. Biochem. 57:1243, 1993), a nucleotide sequence of Streptomyces nitrosporeus a-amylase inhibitor (U. S. Patent No. 5,494,813, Hepher and Atkinson, issued February 27,1996); an insect-specific hormone or pheromone such as an ecysteroid and juvenile hormone, a variant thereof, a mimetic based thereon, or an antagonist or agonist thereof (Hammock et al., Nature 344:458, 1990); an insect-specific peptide or neuropeptide which, upon expression, disrupts the physiology of the affected pest (Regan, J. Biol. Chem. 269:9, 1994); an insect-specific venom produced in nature by a snake, a wasp, etc.(Pang et al., Gene 116:165, 1992), an enzyme involved in the modification, including the post-translational modification, of a biologically active molecule; for example, a glycolytic enzyme, a proteolytic enzyme, a lipolytic enzyme, a nuclease, a cyclase, a transaminase, an esterase, a hydrolase, a phosphatase, a kinase, a phosphorylase, a polymerase, an elastase, a chitinase and a glucanase, whether natural or synthetic(PCT application WO 93/02197), which discloses the nucleotide sequence of a callase gene; DNA molecules which contain chitinase-encoding sequences (Kramer et al., Insect Biochem. Molec. Biol. 23:691, 1993), who teach the nucleotide sequence of a cDNA encoding tobacco hookworm chitinase, and (Kawalleck et al., Plant Molec. Biol. 21 :673, 1993), who provide the nucleotide sequence; a molecule that stimulates signal transduction (Botella et al., Plant Molec. Eiol. 24:757, 1994) of nucleotide sequences for mung bean calmodulin cDNA clones, and (Griess et al., Plant Physiol, 104:1467, 1994), who provide the nucleotide sequence of a maize calmodulin cDNA clone; a sequence of the parsley ubi4-2 polyubiquitin gene peptide (PCT application W095/16776); a membrane permease, a channel former or a channel blocker (Jaynes et al., Plant Sci 89:43, 1993), of heterologous -expression of a cecropin-P, lytic peptide analog to render transgenic tobacco plants resistant to Pseudomonas solanacearum; a viral-invasive protein or a complex toxin derived therefrom, for example, the accumulation of viral coat proteins in transformed plant cells imparts resistance to viral infection and/or disease development effected by the virus from which the coat protein gene is derived, as well as by related viruses (Beachy et al., Ann. rev. Phytopathol. 28:451, 1990); an insect-specific antibody or an immunotoxin derived therefrom (Cf. Taylor et al., Abstract W97, Seventh Int'l Symposium on Molecular Plant-Microbe Interactions (Edinburgh, Scotland) (1994)); a virus-specific antibody (Tavladoraki et al., Nature 366:469 (1993), who show that transgenic plants expressing recombinant antibody genes are protected from virus attack); a developmental-arrestive protein produced in nature by a pathogen or a parasite by solubilizing plant cell wall homo-a-I ,4-D-galacturonase (Lamb et al., Biotechnology 10:1436, 1992); a gene encoding a bean endopolygalacturonase-inhibiting protein (Toubart et al., Plant J. 2:367, 1992); a development-arrestive protein produced in nature by a plant (Logemann et al., Biotechnology 10:305, 1992); genes that confer resistance to a herbicide, for example, a herbicide that inhibits the growing point or meristem, such as a mutant ALS and AHAS enzyme (Lee et al., EMBO J. 7:1241, 1988; Miki et al., Theor. Appl. Genet. 80:449, 1990), glyphosate resistance imparted by mutant 5-enolpyruvl-3- phosphikimate synthase (EPSP) and aroA genes, respectively) and other phosphono compounds such as glufosinate (phosphinothricin acetyl transferase, PAT and Streptomyces hygroscopicus phosphinothricin-acetyl transferase, bar, genes), and pyridinoxy or phenoxy proprionic acids and cycloshexones (ACCase inhibitor-encoding genes) (U.S. Patent No. 4,940,835, Shah, et al.), which discloses the

nucleotide sequence of a form of EPSP which can confer glyphosate resistance, the nucleotide sequence of a phosphinothricin-acetyl-transferase gene in European application No. 0 242 246 to Leemans et al., DeGreef et al., Bioflechnology 7:61 (1989); genes conferring resistance to phenoxy proprionic acids and clycloshexones, such as sethoxydim and haloxyfop, including Accl-S1 , Accl-S2 and Accl-S3 genes (Marshall et al., Theor. Appl. Genet. 83:4:35, 1992); a herbicide that inhibits photosynthesis, such as a triazine (psbA and gs+ genes) and a benzonitrile (nitrilase gene) (Przibila et al., Plant Cell 3:169, 1991); mutant psbA genes; nitrilase genes (U. S. Patent No. 4,810,648 to Stalker); modified fatty acid metabolism genes, for example, an antisense gene of stearoyl-ACP desaturase to increase stearic acid content of the plant (Knutzon et al., Proc. Natl. Acad. Sci. U.S.A. 89:2624, 1992); a phytase- encoding gene to enhance breakdown of phytate, adding more free phosphate to the transformed plant (Van Hartingsveldt et al., Gene 127:87,1993); an Aspergillus niger phytase gene; a gene coding for an enzyme that alters the branching pattern of starch; also (Shiroza et al., J. BacteoL 170:810, 1988) (nucleotide sequence of Streptococcus mutans fructosyltransferase gene), (Steinmetz et al., Mol. Gen. Genet. 20:220, 1985) (nucleotide sequence of Bacillus subtilis levansucrase gene), (Pen et al., Biotechnology 10:292, 1992) (production of transgenic plants that express Bacillus lichenifonnis mamylase), (Elliot et al., Plant Molec. Biol. 21 515, 1993) (nucleotide sequences of tomato invertase genes), Sergaard et al., J. Biol. Chem. 268:22480, 1993) (site-directed mutagenesis of barley a-amylase gene), and (Fisher et al., Plant Physiol. 102: 1 045. 1993) (maize endosperm starch branching enzyme II).

As can be seen, well more than a representative list of transgenes sufficient to comply with the written description requirement were well known prior to filing. There is no basis in the written description requirement for requiring Applicants to limit the claims to these examples or for requiring additional examples. The specification ***need not disclose what is well-known*** to those skilled in the art and ***preferably omits*** what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Literally tens of thousands of different genes were known to those of skill in the art prior to the filing of the instant application, each of which could be introduced into variety 0137335 using any of the many well known techniques for soybean transformation or soybean breeding discussed in the application. Applicants need not recite every conceivable transgene, as is apparently being required by the Examiner here, and doing so would serve no statutory basis. The written description requirement has never required *ipsis verbis* recitation in the specification of every possible iteration of a

claim. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Were this not the case, each patent application would need to be thousands of pages long to include a recitation of what is already well known in the art. However, this is not the law and therefore removal of the rejection is respectfully requested.

In view of the foregoing, removal of the rejections under 35 U.S.C. §112, first paragraph is respectfully requested.

E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Enablement

(1) The Action rejects claims 1-27 under 35 U.S.C. §112, first paragraph, for lack of enablement based on the need for a deposit of seed of the claimed soybean variety.

In response, Applicant notes that a deposit of 2,500 seeds of the claimed soybean variety will be made with the ATCC in accordance with all of the relevant rules for a deposit, including irrevocable release of seed to the public without condition. The corresponding deposit information will be inserted into the claims and specification. A declaration demonstrating compliance with the rules will also be submitted.

In light of the foregoing, Applicant respectfully requests that the rejection be withdrawn.

(2) The Action rejects claims 9-13 and 27 as lacking enablement. For example, it is asserted that claims to producing single locus conversions are not enabled. Applicants traverse as all of the claims recited involve routine breeding techniques well known in the art and all of the materials employed in the techniques are fully provided by the specification.

In addition Applicants note that the specification includes an example describing a conversion that was made with a proprietary soybean variety. This example gives the breeding history of the conversion that was made, including a description of multiple backcrosses. The example describes exactly the type of process one of skill in the art could use to prepare

conversions of the instant variety. The specification provides in great detail further guidance for creation of converted plants, including backcrossing. The techniques recited are also all well known in the art (*e.g.*, Poehlman *et al.*, 1995; Fehr, 1987; Sprague and Dudley, 1988). No basis has been provided to demonstrate why this example alone is not fully enabling as the procedures used in the example may be used to introgress any trait within the scope of the claims.

The only basis alleged by the Examiner for the rejection is several references said to show the difficulty of making male sterile or single locus converted plants. However, these references have not been shown to have any relevance to soybean plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established, as is specifically required to demonstrate a *prima facie* case of non-enablement.

Soybean breeding is extremely advanced and well known in the art. This is due in large part to the fact that soybeans are one of the world's major crops and largest seed crops. North American farmers alone plant tens of millions of acres of soybeans at the present time and there are extensive national and international commercial soybean breeding programs. It is respectfully submitted that this is not true of petunias, sugar beets and tomatoes.

In conclusion, no basis has been provided to conclude why anything other than routine experimentation using the well known techniques would be required. The enablement of the claims has therefore been established and removal of the rejection is respectfully requested.

F. Rejection Under 35 U.S.C. §102(b)/103(a)

The Action has rejected claims 1-27 under 35 U.S.C. §102(b)/103(a) as allegedly anticipated or, in the alternative, obvious over variety 93127627010 from US 5,650,552. Applicants respectfully traverse.

Applicants initially note that the two described varieties differ at least in leaf color, possession of a Roundup Ready™ gene and oil plus protein content. In regard to the latter, Applicants note that while the protein and oil content of 93127627010 is apparently not disclosed in the patent, the current specification explains that variety 0137335 contains an unusually high seed protein plus oil content in combination with high yield that was not previously achievable. For example, the specification explains that the prior art has not provided high yielding agronomically elite soybean varieties with the very high levels of mean whole seed total protein content plus oil exhibited, presumably because of the negative correlation observed between these traits. This is illustrated in Tables 5-7 of the specification, which show that the current variety exhibits extremely high levels of seed protein plus oil seed protein plus oil contents of 65% and greater, exceeding that of nearly every one of the numerous lines shown in head to head comparisons while also exhibiting high yield. The cited varieties therefore does not teach all elements of the current claimed variety and cannot serve as the basis for an anticipation rejection.

To the extent that unexpressed inherent characteristics of the cited variety form the basis of the anticipation rejection, it is noted by Appellants that these characteristics must necessarily flow from the prior art. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is

necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Here, Applicants have affirmatively shown that the characteristics of the cited variety are not the same as those of the claimed variety. The burden under 35 U.S.C. §102 has thus not been met.

With regard to the alternative obviousness rejection, it is noted that, in order to establish a *prima facie* case of obviousness, three criteria must be met: (1) there must be some motivation or suggestion in the cited prior art or in the knowledge generally available to one of skill in the art to combine the teachings to arrive at the invention, (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all claim limitations. *See In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991), *see also*, M.P.E.P. § 2142. All three of these criteria are missing in the instant rejection. First, there is no motivation or suggestion in the prior art to arrive at the invention and no rationale for such a motivation has been alleged without applying an "obvious to try" type rationale. This approach has been rejected by the Federal Circuit. *See In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Second, one of skill in the art would have no reasonable expectation of success in selecting a set of plants that could be crossed to arrive at the claimed plants. For example, there is no indication or showing that such a set of plants even exists, let alone the motivation for one of skill in the art to cross the plants. Again, the soybean variety 0137335 is novel. Finally, the prior art does not teach or suggests all of the claim limitations. Removal of the rejection is thus respectfully requested.

G. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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Date: August 2, 2006